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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,198	03/01/2002	Daryl Real	5407/1J328-US1	8576
7590	08/31/2004		EXAMINER	
DARBY & DARBY P.C. 805 Third Avenue New York, NY 10022			JAGOE, DONNA A	
		ART UNIT	PAPER NUMBER	
			1614	
DATE MAILED: 08/31/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,198	REAL ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 May 2004.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-6 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/26/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

Claims 1-6 are pending in this application.

Response to Arguments

Applicant's arguments, see pages 7-13, filed 26 May 2004, with respect to the rejection(s) of claim(s) 1-6 under 35 USC 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the IDS submitted 26 May 2004.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Musser et al.¹, Trottier et al. ², J. Arthington ³ Samland et al. 1999(CB).

The claims are drawn to a method of enhancing the reproductive performance of a sow which comprises feeding to a sow during at least two gestation periods and optionally during lactation, breeding and/or prebreeding, amounts of L-carnitine or a salt thereof and a trivalent chromium salt sufficient to enhance the reproductive performance of said sow. Dependent claims are drawn to the amounts of L-carnitine and trivalent chromium salts in mg/day or ug/day and a method of feeding sow diet supplemented with L-carnitine and trivalent chromium salts.

Musser et al. teach L-carnitine added in an amount of 50 ppm to sow diet to assess gestation and lactation and litter performance. L-carnitine increased litter birth and weaning weights (see abstract). After weaning, sows were monitored once daily for estrus. *Subsequent* farrowing rate, total number of pigs born and number born alive

¹ Effects of L-Carnitine on Performance of Gestating and Lactating Sows, Swine Day 1999 (IDS from 6/20/03 document #2).

² Effect of Supplemental Chromium Tripicolinate on Sow Productivity and Blood Metabolites, 1998 (IDS from 12/18/2002, document #9).

³ Millennium Technologies The Original L-Carnitine/Chromium Picolinate Supplement, How and Why it Works? 4/27/00, (IDS from 5/8/02, document #10)

were also determined. Table 5 demonstrates the effects of L-carnitine on subsequent reproductive performance where the number of total born pigs increased and the number of pigs born alive increased.

It does not teach the addition of trivalent chromium salts.

Trottier et al. teach chromium tripicolinate to sow diets to increase sow productivity through increasing litter size. 200 ppm of chromium tripicolinate fed to sows increase litter size and reduced wean to estrus interval, thus enhancing sow reproductive performance (see summary). Sows remained on the study for *three consecutive farrowings* (page B-2, paragraph 2). There is a noted improvement in litter size in cycle 2 with continuous chromium supplementation at 200 ppm (page B-3, paragraph 4).

It does not teach the addition of L-carnitine.

Samland et al. teach the addition of L-carnitine and chromium nicotinate (a trivalent salt) in the amount of 200 ppm of each to a sow diet (page 33, column 1, paragraph 2). Samland et al. teach that L-carnitine and chromium nicotinate are two regulatory nutrients that influence insulin signaling. Increased insulin secretion has been shown to increase maturation of ovarian follicles and ovulation rate (see abstract). The claims differ in that the combination of L-carnitine and chromium nicotinate is fed to gilts, and not through at least two gestation periods. However, it would have been obvious to supplement animal feed with chromium and L-carnitine motivated by the teaching of Musser et al and Trottier et al. above who teach that individually, L-carnitine and trivalent chromium are beneficial to sow reproductive performance beyond the first

parity. It is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. *In re Kerkhoven* 205 USPQ 1069. The idea for combining said compositions flows logically from their having been individually taught in the prior art. *In re Crockett* 126 USPQ 186, 188.

The fact that a first component is in no way related to the second component, but where each has the same utility, does not detract from the obviousness of combining them. *In re Linder*, 457 F.2d 506, 507 (CCPA 1972). (Holding that it would have been obvious to combine two known dispersants, since one skilled in the art would have expected a mixture of such dispersants to also be a dispersant). Moreover, picking and choosing known components from several references, each which itself discloses a plurality of such components, is permissible where each component has the same individual utility. *In re Dial*, 326 F.2d 430 (CCPA 1964). (Holding that it would have been obvious to have combined four individual stabilizers for halogenated hydrocarbon solutions from three different references, where there was no evidence in the record establishing that Applicant's claimed combination of stabilizers was any more effective or in any way otherwise different in inhibiting the decomposition of halogenated hydrocarbons than any single member of that combination. *Id.* at 432.)

See also *In re Shannon* 148 USPQ 504 (one step laminate is obvious from two step laminate).

Regarding applicants suggestion that these results are unexpected because of the synergy of the two agents, J. Arthington is cited to provide motivation to employ L-

carnitine and chromium picolinate to work synergistically since Arthington teaches that L-carnitine and chromium picolinate work synergistically when fed together to reduce the amount of fat deposition during the protein phase of growth. It does not teach enhancing reproductive performance, however, Arthington teaches that chromium is necessary for optimal insulin function and glucose uptake in cells and L-carnitine aids fatty acid metabolism. Samland et al. (above) teaches that increased insulin secretion has been shown to increase maturation of ovarian follicles and ovulation rate (see abstract). Thus, it would have been obvious to employ synergistic combination of L-carnitine and trivalent chromium to enhance reproductive performance motivated by the teaching of Samland et al. that the synergistic combination of Arthington would increase maturation of ovarian follicles and ovulation rate.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

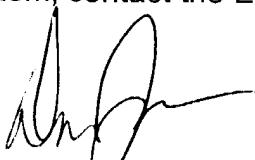
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday and Thursday from 9:00 A.M. - 7:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Donna Jagoe
Patent Examiner
Art Unit 1614

8/26/2004



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